

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)
v. Plaintiff,)
ARCHERDX, INC., ARCHERDX, LLC and) C.A. No. 20-125 (LPS)
INVITAE CORP.,) (CONSOLIDATED)
Defendants.)
) **JURY TRIAL DEMANDED**
) **REDACTED - PUBLIC VERSION**
)

**NATERA, INC.'S LETTER BRIEF IN OPPOSITION TO DEFENDANTS' MOTION
TO STRIKE PORTIONS OF NATERA'S FINAL INFRINGEMENT CONTENTIONS**

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Dear Judge Stark:

Plaintiff Natera, Inc. (“Natera”) submits this opposition to Defendants’ ArcherDX, Inc., ArcherDX, LLC and Invitae Corp.’s (“Defendants”) Motion to Strike Portions of Natera’s Final Infringement Contentions. Defendants have two issues. First, Defendants argue that Natera should not be allowed to assert the corrected ’482 Patent claims because Natera should have corrected the patent claims before filing the lawsuit and anything asserted afterwards is prejudicial. Defendants take this position even though the U.S. Patent Office made the error; Defendants had notice of the corrected claim language by at least April 15, 2020 (the date of the First Amended Complaint) and more than sufficient time to pursue discovery and articulate claim construction positions and defenses. Defendants have not – and cannot – articulate any new claim construction issue: the ’482 Patent corrections pertain to a molecular barcode and sequencing tag. Molecular barcode is a claim limitation in other asserted patent claims (e.g., claim 4 of the ’814 Patent) and sequencing tag was at issue during claim construction and the Court provided a construction for the term.

Second, Defendants argue that Natera should not be permitted to assert additional **dependent** claims, even though Natera served its preliminary infringement contentions almost 10 months ago, before Natera had the benefit of Defendants’ belated technical documents or invalidity contentions. Remarkably bereft from Defendants’ motion is any actual prejudice suffered by Defendants. As demonstrated below, the added dependent claims present no new claim constructions issues as the same terms are in the original set of claims. Further, Defendants’ contention that adding dependent claims is excessive or impermissible lacks merit in view of: (1) Defendants’ rejection of Natera’s original reasonable offer to limit the number of asserted claims and prior art references in September 2020 as part of the CMC process; and (2) Defendants’ addition of 68 new prior art references in their July 26, 2021 Final Invalidity Contentions from their Amended Invalidity Contentions. Defendants have further shown that there was no discovery they could not have pursued, and have already advanced noninfringement positions to the added dependent claims. In *Intellectual Ventures I LLC v. AT&T Mobility LLC*, 2017 WL 658469 at *2 (D. Del. Feb. 14, 2017), the court did not strike an infringement theory (disclosed for the first time two weeks before discovery ended), holding that it was “contained in [the plaintiff’s] timely-served infringement contentions.” *Intellectual Ventures I*, 2017 WL 658469 at *5. As in that case, Natera “permissibly relied” on the Scheduling Order permitting Natera “to finalize infringement contentions after the Court’s claim construction order.”

I. FACTUAL BACKGROUND

When the ’482 Patent issued in March 2020, it incorrectly omitted two limitations from independent claim 1 in a printing error. On April 15, 2020, when Natera first asserted the ’482 Patent by filing its First Amended Complaint (D.I. 17) and again on January 12, 2021, when filing its Second Amended Complaint (D.I. 116), Natera provided the corrected language in its attached claim charts. On June 10, 2021, Natera submitted its request for a certificate of correction for the USPTO’s mistake under 37 C.F.R. § 1.322(a), which the PTO granted on July 13, 2021, clarifying Claim 1, Column 56, Line 45, stating it should read as follows: “--the adaptors each comprise a universal priming site, **wherein (i) the adaptors each comprise a molecular barcode and/or (ii) at least one of the primers comprises a sequencing tag;**--”

The day before, Natera served its Final Infringement Contentions under the Scheduling Order (D.I. 60.) The correct language of Claim 1 of the '482 Patent along with additional asserted dependent claims¹ from the five Asserted Patents were included. On April 30, 2021 and July 26, 2021, Defendants provided their Amended and Final Invalidity Contentions alleging that Natera cannot assert corrected Claim 1 in its Final Infringement Contentions because Natera had not sought to amend its complaint. Defendants' Final Invalidity Contentions also included 68 new prior art references – an over 50% increase in the number of prior art references.

In August, the parties met and conferred regarding Defendants' July 30, 2021 request that Natera withdraw from its Final Infringement Contentions the uncorrected claims of the '482 Patent and added claims. As part of that process, Natera explained that: (i) Defendants had not articulated why Natera is not permitted to add claims to its final contentions, especially since Defendants have had prior notice of these claims and were adding prior art in their Final Invalidity Contentions; and (ii) Claim 1 was properly asserted against Defendants, including through Natera's complaints and infringement contentions. Natera did not agree to withdraw Claim 1, but agreed to file a motion to amend/supplement its complaint, though legally it was not required to do so, *infra*. Defendants stated they would oppose any such motion on August 25, and further filed the instant motion to strike on August 30. (D.I. 301.) Natera filed its motion to amend August 31 (D.I. 304.)

II. LEGAL STANDARDS

Infringement contentions are treated as "initial disclosures" under Federal Rule of Civil Procedure 26(a) and the party alleging infringement is permitted to supplement their contentions. *See United States District Court for the District of Delaware, Default Standard for Discovery § 4(a); Intellectual Ventures I LLC v. AT&T Mobility LLC*, 2017 WL 658469 at *2 (D. Del. Feb. 14, 2017). In assessing the propriety of supplementing discovery, courts focus on "whether a party has provided adequate notice of its legal contentions and their corresponding evidentiary bases." *Lab. Skin Care, Inc. v. Ltd. Brands, Inc.*, 661 F. Supp. 2d 473, 477 (D. Del. 2009).

The determination of whether to exclude evidence is within the discretion of the district court. *See Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) In the Third Circuit, the "Pennypack factors" govern whether late-disclosed evidence should be precluded. These are (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence. *Id.* The "exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Id.*

III. NATERA'S CORRECTED CLAIM 1 OF THE '482 PATENT IS PROPERLY ASSERTED

Defendants' argument of lack of timeliness of the corrected claim language depends

¹ Natera notes that Defendants' Motion to Strike erroneously identifies 9 added dependent claims, although Natera's Final Infringement Contentions added 10 dependent claims.

almost entirely on the formalism of the amended pleading. Natera's supplementation of its infringement contentions to add the corrected claims was timely under the Scheduling Order and there is no lack of diligence or bad faith. Natera disclosed the correct language of claim 1 of the '482 Patent in its First and Second Amended Complaints, filed on April 15, 2020 and January 12, 2021, and again in Natera's Final Infringement Contentions. Thus, Defendants have been on notice since at least April 2020, and there has been no expansion of infringement claims or theories. Defendants' argument that they are "incurably prejudiced" by the ministerial addition of the corrected claims lacks merit. Defendants have already taken discovery with notice of the corrected claims, including presenting claim construction positions and presumably conducted a prior art search consistent with Defendants' proposed constructions and alleged indefiniteness issue. Again, it bears emphasis that there are no new claim construction positions by the correction. Molecular barcode is a claim limitation in other originally asserted patent claims (e.g. claim 4 of the '814 Patent) and "sequencing tag" was at issue during claim construction and the Court provided a construction for the term.

To the extent Defendants complain that Natera may not rely on the certificate of correction because it issued on July 13, 2021 – one day after Natera provided its Final Infringement Contentions – this is form over substance. Natera submitted its request for a certificate of correction for the USPTO's mistake in the printing error under 37 C.F.R. § 1.322(a) on June 10, 2021. The request along with the issued certification of correction is part of the publicly available file history of the '482 Patent easily accessible through the USPTO's website and has also been produced in this action.

Legally, the formalistic action of supplementing the complaint in order for a certificate of correction to apply to post-issuance infringing conduct in a pending action is likely not required. (D.I. 304.) *See, e.g., H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1334 (Fed. Cir. 2014) (Federal Circuit made no holding requiring a party to seek amendment to inject a certificate of correction into ongoing litigation); *Finjan, Inc. v. Proofpoint, Inc.*, No. 13-cv-05808, 2014 WL 6386727 (N.D. Cal. Nov. 14, 2014) (court did not read *H-W Tech.* to be a sea change that requires a party to seek leave to amend to add a certificate of correction where there are claims of ongoing infringement). Nevertheless, Natera acted diligently to supplement within weeks of receiving the Certificate of Correction and meet and confers with Defendants to foreclose any future disputes by filing its Motion to Supplement. (See D.I. 304.)

Finally, Defendants have not presented any legal authority of a *per se* rule prohibiting a patent owner from alleging infringement of both the original uncorrected and corrected claims in the same case simply because a certificate of correction has been issued, so long as each version of the claim is valid. *Traxcell Techs., LLC v. ALE USA Inc.*, Case No. 18-cv-6736, 2019 WL 6910429 at *12 (C.D. Cal. July 30, 2019). Defendants' reliance on *H-W Tech.* is inapposite because that case involved circumstances where the basis for the conclusion that the uncorrected claim could not be asserted began with a substantive determination that the uncorrected claim was invalid. *H-W Tech.*, 758 F.3d at 1333. *H-W Tech.* did not address whether both the valid original and corrected claims could be asserted in the same action assuming validity of the uncorrected claim.

IV. NATERA'S ADDED DEPENDENT CLAIMS IN ITS TIMELY-SERVED INFRINGEMENT CONTENTIONS SHOULD NOT BE STRICKEN

Defendants argue that Natera should not be permitted to assert additional dependent claims across four of its five asserted patents, disclosed in Natera's Final Infringement Contentions. The *Pennypack* factors do not weigh in favor of excluding Natera's added dependent claims from its Final Infringement Contentions.

Natera's supplementation of its infringement contentions to add dependent claims on July 12, 2021 was timely under the Scheduling Order. (D.I. 60.) There has been no "eleventh hour disclosure" here or presence of bad faith or willfulness in adding claims to Natera's final infringement contentions. Natera served its Initial Infringement Contentions on November 11, 2020, without the benefit of Defendants' technical documents and invalidity contentions, and amended its infringement contentions as allowed by the Court's schedule to add new dependent claims after additional information became available.

The added dependent claims add no truly new theories of infringement or claim construction issues. Defendants have long had prior notice of the elements in other asserted claims:

Initial Infringement Contentions	Final Infringement Contentions Added Dependent Claims
'814 patent, Claim 13: The method of claim 1, wherein the concentration of each target-specific primer of the first and/or second PCR is less than 20 nM.	'172 Patent, Claim 11; '482 Patent, Claim 9. The method of claim 1, wherein the concentration of each target-specific primer of the first and/or second PCR is less than 20 nM.
'814 Patent, Claim 15: The method of claim 1, wherein the length of the annealing step of the first and/or second PCR is at least 3 minutes.	'172 Patent, Claim 13; '482 Patent, Claim 11. The method of claim 1, wherein the length of the annealing step of the first and/or second PCR is at least 3 minutes.
'814 Patent, Claim 19: The method of claim 1, wherein the cell-free DNA comprises DNA from mixed origin.	'172 Patent, Claim 17; '220 Patent, Claim 18. The method of claim 1, wherein the cell-free DNA comprises DNA from mixed origin.
'814 Patent, Claim 8: The method of claim 1, wherein the first PCR comprises simultaneously amplifying at least 100 target loci using the universal primer and at least 100 target-specific primers in a single reaction volume.	'482 Patent, Claim 6. The method of claim 1, wherein the first PCR comprises simultaneously amplifying at least 100 target loci using the universal primer and at least 100 target-specific primers in the first reaction volume.
'220 Patent, Claim 7: The method of claim 6, wherein the second PCR comprises simultaneously amplifying between 100 and 5,000 target loci using the second universal primer and between 100 and 5,000 target-specific primers in a single reaction volume.	'814 Patent, Claim 10; '172 Patent, Claim 8. The method of claim 1, wherein the second PCR comprises simultaneously amplifying at least 100 target loci using the universal primer and at least 100 inner target-specific primers in a single reaction volume. '482 Patent, Claim 8. The method of claim 1, wherein the second PCR comprises

	simultaneously amplifying at least 100 target loci using the universal primer and at least 100 inner target-specific primers in a second reaction volume
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There is no prejudice or surprise to Defendants. Natera's Initial Infringement Contentions provided Defendants with sufficient information, giving Defendants a "meaningful opportunity to discover necessary information about the identified components and processes of Defendants' accused products. The disclosure of new infringement theories toward the end of discovery does not require that such theories be stricken. In *Intellectual Ventures I*, the court did not strike an infringement theory (disclosed for the first time two weeks before discovery ended), holding that it was "contained in [the plaintiff's] timely-served infringement contentions." *Intellectual Ventures I*, 2017 WL 658469 at *5. So too here, Natera "permissibly relied" on the Scheduling Order "to finalize infringement contentions after the Court's claim construction order." Presumably Defendants rely upon the same Scheduling Order to justify dumping into the case five weeks before the close of fact discovery 68 new prior art references as part of its July 26 Final Invalidity Contentions – all the while rejecting Natera's original CMC proposal to limit the number of claims and prior art references.

Defendants provided a second supplemental response to Natera's Interrogatory No. 5 (which seeks a description of the legal and factual basis for Defendants' contention that any or all claims of the Asserted Patents are not infringed) on August 30, 2021, stating grounds for noninfringement of the added asserted claims. Ex. A, Defendants' Second Supplement Response to Interrogatory No. 5. These reflect many of the same arguments for non-infringement as Defendants' provided in their first supplemental response to this interrogatory on December 18, 2020. *Id.* For example:

- [REDACTED]
- [REDACTED]
- [REDACTED]

Id. As such, with clear non-infringement grounds articulated and adding 68 new references on claim elements reflected in initially asserted claims, Defendants' argument that it has somehow "lost the opportunity to litigate the case" lacks merit. (D.I. 302 at *3.)

Finally, Defendants' complaint that Natera's claims across five patents is "too many" lacks merit. Defendants do not propose any commensurate need to narrow their own case of over 142 references, a near doubling from their First Amended Invalidity Contentions served a few months ago in April. Defendants further refused any narrowing of the case from the outset and have continued to expand their invalidity contentions throughout discovery. A motion to strike is not the proper procedural means to request a narrowing of claims, but to the extent the Court orders the parties to meet and confer as to any narrowing, Natera respectfully requests the Court also order Defendants to narrow significantly their prior art defenses.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/lo

Attachment

cc: Clerk of the Court (*via* CM/ECF)
All Counsel of Record (*via* CM/ECF and e-mail)